Paper No. 13

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte RICHARD S. BLUME

Appeal No. 2002-1361
Application No. 09/476,822

ON BRIEF

Before SCHEINER, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 8-13. Claim 8 is representative of the subject matter on appeal, and reads as follows:

8. A method for detecting Helicobacter pylori infection in a human, comprising:

(a) gargling with a designated volume of sampling liquid, without expectorating, to provide an oral liquid sample,

(b) tilting the head forward and opening the mouth, such that said oral liquid sample enters a collection container,

(c) acidifying said oral liquid sample in said collection container such that the pH of said oral liquid sample is below about 5.0 but above about 2.5,

(d) contacting said oral liquid sample in said collection container with a urease detecting pad containing urease substrate,

(e) observing said urease detecting pad for a color change or lack of color change, and

(f) correlating said color change or lack of color change with presence or absence of Helicobacter Pylori infection in said human,

whereby said detecting of Helicobacter Pylori infection is performed without incubating of said oral liquid sample.

Claims 8-13 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a disclosure that is not enabling. Claims 8-13 also stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. After careful review of the record and consideration of the issues before us, we reverse all of the rejections of record.

DISCUSSION

Claims 8-13 stand rejected under 35 U.S.C. § 112, first paragraph, as based on a disclosure that is not enabling.

According to the rejection,

> [a] number of features are critical or essential to the practice of the invention, but not included in the claim[s] is not enabled by the disclosure. In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

> A reading of the specification reveals the following features are critical to the invention as described:
> 1. The pad has a color pH indicator; and
> 2. The pH of the sampling liquid is 2.5 – 5, after sampling if the pH remains under 5 for 1-2 hours, H. Pylori is not present, if the pH rises to above 7 after 1-2 hours, H. Pylori is present. Further, it would appear the collection container is not critical to the invention.

Examiner's Answer, page 4.

The burden is on the examiner to set forth a prima facie case of unpatentability. See In re Glaug, 283 F.3d 1335, 1338, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002). We find that the examiner has not done so.

The examiner's first concern appears to be that the claims do not specifically recite that the pad has a color pH indicator. The claims, however, specify that the pad is a urease detecting pad containing urease substrate. The specification describes the urease detecting pad as having a pH indicator element that is in a dry state and that undergoes a color change reflecting the increase in pH produced by the urease in the sample acting on the urease substrate. See Specification, pages 28-29. Thus, the examiner's concern is unfounded, as the recitation of a urease detecting pad implicitly requires that the pad contain a color pH indicator.

We are not sure what the examiner is objecting to with the comment that "[t]he pH of the sampling liquid is 2.5 – 5, after sampling if the pH remains under 5 for 1-2 hours, H. Pylori is not present, if the pH rises to above 7 after 1-2 hours, H. Pylori is present." If the examiner is objecting to that the claim does not specifically recite how the color changes when the pH of the sample increases in response to the presence of H. Pylori, the specification provides guidance and

examples of such pH indicators, see Specification, pages 29-30, and as the claims recite correlating the color change or lack thereof to the presence or absence of H. Pylori in the sample, there is no need to add any specific color change to the claims.

The examiner's rejection under 35 U.S.C. § 112, first paragraph, is reversed.

Claims 8-13 also stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention.

According to the examiner,

> [i]n claim 8 and all occurrences, "designated" volume is unclear as to who and why designated the volume. There may be some confusion regarding the contacting and incubating steps. If no incubating such as in claim 9(f) takes place, it would appear the invention would not work because a waiting period is required. The correlating steps as written do not state directly what the correlation may be. Further what the color change may be based upon is not set forth.

Examiner's Answer, page 5.

If we understand the rejection correctly, the examiner's first concern is the use of "designated" renders the claim indefinite because one skilled in the art would not understand who designated the volume. The specification, however, defines the volume as "5 to 10 ml or more," id. at 18, thus one of skill in the art would understand the meaning of designated.

The examiner's second concern appears to be that there is no specific incubation step. The rejection states that "[i]f no incubating such as in claim 9(f)

takes place, it would appear the invention would not work because a waiting period is required." (Examiner Answer, page 5). If the invention would not work, however, that is more properly a first paragraph, enablement rejection, and not a second paragraph rejection. Moreover, the specification defines an incubating step as incubation of the sample in selective growth media over a period of days, id. at 12, which is different than a "waiting step" to allow the urease substrate to react with the urease.

The examiner's third concern about the correlating step is not understood, as the claims recite the presence or absence of a color change is correlated to the absence or presence of Helicobacter Pylori infection in the sample.

The examiner's last concern appears to be what causes the color change is not specifically set forth in the claims. As discussed above with respect to the first paragraph rejection, the recitation of a urease detecting pad implicitly requires that the pad contain a color pH indicator, and thus one skilled in the art would understand the claims.

The examiner's rejections under 35 U.S.C. § 112, second paragraph, are reversed.

CONCLUSION

The rejection of claims 8-13 under 35 U.S.C. § 112, first paragraph, as being based on a disclosure that is not enabling, is reversed. The rejection of claims 8-13 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention, is also reversed. The application is being returned to the examiner for further proceedings not inconsistent with this opinion.

REVERSED

Toni R. Scheiner Administrative Patent Judge	)
	) BOARD OF PATENT
Eric Grimes Administrative Patent Judge	) APPEALS AND
	) INTERFERENCES
Lora M. Green Administrative Patent Judge	)

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